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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,790	07/26/2000	Stuart W. Peltz	601-1-044DIV	8302
23869	7590	10/19/2005	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 10/19/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/625,790

Applicant(s)

PELTZ ET AL.

Examiner

David J. Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005 and 29 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7,35-43,48-50 and 54-66 is/are pending in the application.
- 4a) Of the above claim(s) 7,35-43,48-50 and 54-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Appendices A and B.

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## **DETAILED ACTION**

### ***Status of the Application***

**[1]** A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/2005 has been entered.

**[2]** The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

**[3]** Claims 7, 35-43, 48-50, and 54-66 are pending in the application.

**[4]** Applicants' amendments to the claims, filed on 4/18/2005 and on 7/29/2005, are acknowledged. The claim amendment filed on 4/18/2005 fails to satisfy the requirements of 37 CFR 1.121 for the reasons set forth in the Office communication mailed on 6/28/2005. The claim amendment filed on 7/29/2005 appears to correct the deficiency and replaces all prior versions and listings of the claims.

**[5]** Applicants' arguments filed on 4/18/2005 and on 7/29/2005 are acknowledged. Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[6] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

***Election/Restriction***

[7] Applicants' election with traverse of Group II in the reply filed on 3/7/2005 is acknowledged. In the responses filed on 3/7/2005, 4/18/2005, and 7/29/2005, applicants request that the claims of Groups I and II be rejoined. Upon further consideration, applicants' request is granted and the claims of Groups I and II are rejoined and are being co-examined on the merits.

[8] With regard to Groups III-XII, the requirement is still deemed proper and is therefore made FINAL.

[9] Claims 7, 35-43, 48-50, and 54-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[10] Claims 57-66 are being examined on the merits.

***Claim for Domestic Priority***

[11] Applicants' claim for domestic priority under 35 USC § 120 to US non-provisional application 08/724,992, filed on 10/4/1996, now abandoned, is acknowledged.

Applicants' claim for domestic priority under § 119(e) to US provisional application 60/005,041, filed 10/6/1995, is acknowledged.

***Specification/Informalities***

**[12]** The objection to the specification for not updating the status of a prior application to which domestic priority is claimed is maintained for the reasons of record. It is noted that an amendment to the specification was filed on 3/7/2005 to correct this deficiency. However, this amendment was not entered for those reasons set forth in the Advisory action mailed 3/28/2005. Applicants are requested to re-submit a similar amendment to the specification in the response to this Office action. Applicants are reminded that any amendment to the specification should comply with the revised amendment practice under 37 CFR 1.121.

**[13]** The objection to the specification as containing sequence disclosures that fail to comply with the requirements of 37 CFR 1.821 to 1.825 is maintained for the reasons of record. It is noted that an amendment to the drawings was filed on 3/7/2005 to correct this deficiency. However, this amendment was not entered for those reasons set forth in the Advisory action mailed 3/28/2005. Applicants are requested to re-submit a similar amendment to the drawings in the response to this Office action. Applicants are reminded that any amendment to the drawings should comply with the revised amendment practice under 37 CFR 1.121.

***Claim Rejections - 35 USC § 112, Second Paragraph***

**[14]** Claims 57-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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**[a]** Claim 57 (claim(s) 58-59 and 61-66 dependent therefrom) is indefinite in the recitation of "virus using programmed -1 ribosomal frameshifting" as it is unclear from the specification and the claims as to the intended scope of viruses that use programmed -1 ribosomal frameshifting. It is suggested that applicants clarify the meaning of the term in the claim.

**[b]** Claims 57 (claim(s) 58-60 and 65-66 dependent therefrom), 61, and 63 are indefinite in the recitation of "sparsomycin" as it is unclear as to the structure or structures that are intended as being encompassed by the term. The structure of sparsomycin according to CAS Registry is shown in Appendix A and the structure of sparsomycin according to Sigma Aldrich is shown in Appendix B. The two structures are both referred to as "sparsomycin," however they are not identical. As such, it is unclear as to whether applicants intend for the term to encompass one particular structure or both of the structures. It is suggested that applicants clarify the meaning of the term "sparsomycin."

***Claim Rejections - 35 USC § 112, First Paragraph***

**[15]** Claims 59 and 63-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description".

Claim 59 limits the virus that is treated by the claimed method to retroviruses, coronaviruses, paramoxyviruses, astroviruses, and totiviruses. In the response filed on 7/29/2005, applicants point to canceled claim 46 as showing support for the recited limitation. Claim 46 was added in the amendment filed on 8/13/2004. The examiner can find no showing of support for canceled claim 46 in the original application and thus it follows that there is no showing of support in the original application for claim 59. It should also be noted that canceled claim 46 recites only retroviruses, astroviruses, and totiviruses.

Claim 63 limits the concentration of sparsomycin to "about 0.52  $\mu$ M to about 2.6  $\mu$ M." Claim 64 limits the concentration of anisomycin to "about 0.755  $\mu$ M to about 3.8  $\mu$ M." In the responses filed on 4/18/2005 and 7/29/2005, applicants point to Figures 16(A) and (B) as showing support for these limitations in the claims. Figure 16(A) shows the effects of 755 nM, 1.5  $\mu$ M, and 3.8  $\mu$ M anisomycin on -1 ribosomal frameshifting in certain *Saccharomyces cerevisiae* wild-type and mutant cells. Figure 16(B) shows the effects of 520 nM, 1  $\mu$ M, and 2.6  $\mu$ M sparsomycin on -1 ribosomal frameshifting in certain *Saccharomyces cerevisiae* wild-type and mutant cells. As Figures 16(A) and (B) disclose only *specific* antibiotic concentrations that are used in *specific* cell types, the

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figures fail to support the recited ranges of concentrations used to treat a viral infection in any eukaryotic cell.

Claim 65 limits the concentration of anisomycin or sparsomycin to "1 ng/mL or less." Claim 66 limits the effect of the 1ng/mL concentration as being "effective to decrease viral titers in the cells by about 70-80%." In the responses filed on 4/18/2005 and 7/29/2005, applicants point to Figure 15(A) as showing support for this limitation in the claims. Figure 15(A) shows the effects of 10 pg/mL, 100 pg/mL, and 1 ng/mL anisomycin and sparsomycin on HIV titer in human cells. As Figure 15(A) fails to disclose the claimed method at a concentration of "1 ng/mL or less," including any concentration less than 1 ng/mL, and fails to disclose the use of anisomycin and sparsomycin against any virus in any eukaryotic cells, the figure fails to support the recited range of concentrations.

Claim 66 limits the effect of the 1ng/mL concentration as being "effective to decrease viral titers in the cells by about 70-80%." In the responses filed on 4/18/2005 and 7/29/2005, applicants point to Figure 15(B) as showing support for this limitation in the claims. Figure 15(B) shows the effect of 10 pg/mL, 100 pg/mL, and 1 ng/mL anisomycin and sparsomycin on HIV titer in human cells as a percentage of no drug control. As Figure 15(A) fails to disclose the claimed method at a concentration of "1 ng/mL or less," fails to show a decrease in viral titer of 70-80% for anisomycin and 70-80% for sparsomycin, and fails to disclose the use of anisomycin and sparsomycin against any virus in any eukaryotic cells, the figure fails to support the recited range of decreased viral titer.



Applicants are invited to show support for the recited limitations.

**[16]** Claims 57-59 and 61-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating L-A and M<sub>1</sub> infection in yeast cells and HIV infection in human cells by administering anisomycin or sparsomycin, does not reasonably provide enablement for a method for treating any viral infection, optionally any RNA viral infection or any infection of the family of viruses listed in claim 59, that uses -1 ribosomal frameshifting in any eukaryotic cells by administering anisomycin or sparsomycin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation is required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). MPEP 2164.04 states, "[w]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection" and that "[t]he language should focus on

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those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims." Accordingly, the Factors most relevant to the instant rejection are addressed in detail below.

The breadth of the claims: Claims 57-58 are so broad as to encompass a method of treating any viral infection, optionally any RNA viral infection or any infection of the family of viruses listed in claim 59, that uses -1 ribosomal frameshifting in any eukaryotic cell both *in vitro* and *in vivo* by administering anisomycin or sparsomycin. As noted above, it is unclear from the claims and the specification as to those viruses that do and do not use -1 ribosomal frameshifting. The enablement provided by the specification is not commensurate in scope with the claims with regard to the eukaryotic cells/viral infections that are treated as encompassed by the claims. In this case, the specification is enabling only for a method of treating L-A and M<sub>1</sub> infection in yeast cells and HIV infection in human cells by administering anisomycin or sparsomycin.

The state of the prior art; The level of one of ordinary skill; and The level of predictability in the art: At the time of the invention, a method for treating HIV in humans by administering anisomycin was known in the prior art (see Japanese Patent JP 63146818; cited in the 5/14/2004 Office action). However, Aaronson et al. (*Science* 183:422-424) report that treatment of mouse BALB/c cells infected with sarcoma virus with either anisomycin or sparsomycin actually leads to viral induction (p. 422, Table 1). Aaronson et al. propose that these antibiotics interfere with a protein inhibitor of viral

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induction (p. 423, right column, top). Also, Ash et al. (*Antimicrob Agents Chemother* 25:443-445) teaches that sparsomycin is toxic to HeLa cells and mice, even at low doses (p. 444, right column and Figure 1). Thus, it is highly unpredictable as to the effects of administering anisomycin or sparsomycin to any eukaryotic cell infected with a virus that uses  $-1$  ribosomal frameshifting either *in vitro* or *in vivo*. Also, while applicants' results in Figure 15 may suggest that a 1 ng/mL, 100 pg/mL, or 10 pg/mL concentration of anisomycin or sparsomycin result in reduced HIV titer in a eukaryotic cell line, *i.e.*, *in vitro*, it is highly unpredictable as to whether these concentrations of anisomycin or sparsomycin would be effective in treating HIV in eukaryotic cells *in vivo*, particularly as a skilled artisan would recognize that results obtained using cells in culture frequently do not correlate with those results obtained *in vivo*.

The amount of direction provided by the inventor and The existence of working examples: The specification discloses only a single working example of the claimed method, *i.e.*, *in vitro* treatment of an HIV-infected human cell line with anisomycin or sparsomycin (see Figure 15). Other than this single working example, the specification fails to provide guidance regarding the ability of anisomycin or sparsomycin to inhibit other viruses that use  $-1$  ribosomal frameshifting or inhibition of viral growth *in vivo*. In view of the teachings of Aaronson et al., it is highly unpredictable as to whether the single working example of treating HIV-infected human cells can translate into a successful method of treatment for infections of other eukaryotic cells caused by other viruses that use  $-1$  ribosomal frameshifting. Of relevance to the instant rejection is applicants' position, which appears to be that only those *specifically* disclosed working

examples in Japanese Patent JP 63146818 are enabled (see p. 14, last paragraph, lines 3-4 of the response filed on 7/29/2005), although the reference discloses that the method is applicable to other viruses as well, including HIV.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure: As noted above, at the time of the invention, a method for treating HIV in humans by administering anisomycin was known in the prior art as evidenced by Japanese Patent JP 63146818. However, neither the specification nor the claims defines those viruses that use -1 ribosomal frameshifting. Thus, a skilled artisan must first identify the viruses that can potentially be treated using anisomycin or sparsomycin. Next, in view of the high level of unpredictability, one must test all eukaryotic cells with all viruses that use -1 ribosomal frameshifting in order to determine those that can be successfully treated with anisomycin or sparsomycin. Such experimentation was not routine in the art at the time of the invention.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of experimentation, it is the examiner's position that undue experimentation would be necessary for a skilled artisan to make the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological

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characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**[17]** Claims 57-60, 62, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent JP 63146818 as evidenced by Minassian et al. (US Patent 5,254,457).

It is noted that claim 57 recites, “[a] method comprising treating eukaryotic infections caused by viruses using programmed –1 ribosomal frameshifting by...”

Because the phrase “comprising treating eukaryotic infections caused by viruses using programmed –1 ribosomal frameshifting” does not appear to be intended as an active method step, this phrase has been interpreted as being the preamble of the claim.

Thus, the claims are drawn to (in relevant part) a method for treating eukaryotic infections caused by viruses using programmed –1 ribosomal frameshifting by exposing eukaryotic cells infected with a virus that uses –1 ribosomal frameshifting to anisomycin.

As stated in a previous Office action, JP 63146818 teaches a method for treating viral infections by administering anisomycin, including the AIDS virus (see particularly p. 4 of the English translation of JP 63146818, which was attached to the Office action mailed 5/14/2004). JP 63146818 teaches the dosage of anisomycin can be 0.25 micrograms/mL (p. 3 of the translation), which, using 265.31 g/mole as the molecular weight of anisomycin, is 0.94 micromoles/L.

Minassian et al. teaches that HIV-1 is "the etiological agent of the acquired immunodeficiency syndrome (AIDS)" (column 1, lines 18-19). Thus, one of ordinary skill in the art at the time of the invention would have recognized that AIDS itself is not a virus, but is the result of HIV-1 infection.

This anticipates claims 57-60, 62, and 64 as written.

**RESPONSE TO ARGUMENT:** In the response filed on 4/18/2005, applicants argue: 1) there is no mention of -1 ribosomal frameshifting in the JP patent and as such, maintaining the rejection is improper; 2) the JP patent teaches a general method for treating viruses that do not use -1 programmed ribosomal frameshifting, which teaches away from the claimed invention; 3) applicants have found that anisomycin cannot be used to treat all viruses included in the families listed in the JP patent; 4) although the JP patent lists AIDS as one of the viruses that can be treated with anisomycin, the JP patent lists "virtually all" DNA and RNA virus families and one of ordinary skill in the art would not have been led to treat viruses using -1 programmed ribosomal frameshifting; 5) inherency is not a proper basis for rejection as nothing in the prior art suggests using anisomycin to treat viruses using -1 programmed ribosomal

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frameshifting; 6) the JP patent is not an enabling reference because there is a lack of working examples directed to the treatment of viruses using –1 programmed ribosomal frameshifting and guidance and undue experimentation would have been required; 7) in view of its teachings, the JP patent would not have led one of ordinary skill in the art to practice the claimed invention.

Applicants' arguments are not found persuasive. In response to arguments 1) and 5), the JP document need not teach that the viruses treated using anisomycin use –1 programmed ribosomal frameshifting. As noted in previous Office actions, this is an inherent feature of the viruses that infect the subject that is treated by the administration of anisomycin in accordance with the method of the JP document. MPEP 2112 makes clear that "[t]here is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference." Applicants acknowledge that the JP document teaches treatment of the AIDS virus, *i.e.*, HIV, using anisomycin. Thus, in accordance with MPEP 2112, there is no requirement that the JP document disclose that the AIDS virus, *i.e.*, HIV, uses –1 programmed ribosomal frameshifting, only that HIV use –1 programmed ribosomal frameshifting, which according to applicants, it does (p. 35, lines 11-12).

In response to arguments 2), 3), 4), 6), and 7), while the JP document may disclose certain viruses that do not use –1 programmed ribosomal frameshifting, the JP document expressly discloses a method for treating at least one virus that does use –1 programmed ribosomal frameshifting, *i.e.*, HIV (p. 4). MPEP 2121 states, [w]hen the

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reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability." In this case, applicants have provided no facts to rebut the presumption of operability of the method of the JP document. While it is acknowledged that the JP document does not specifically disclose an example of treating eukaryotic cells infected with HIV, the reference discloses specific ranges of dosages (p. 3 of the translation), including specific dosages encompassed by the claims, specific methods of administration (p. 3 of the translation), specific formulations (pp. 3-4 of the translation) and methods for determining whether the anisomycin was effective at treating viral infection (pp. 5-6 of the translation). In the absence of facts to rebut the presumption of operability of the method of the JP document, the method as disclosed therein is presumed to be effective at treating viral infection, including HIV.

**[18]** Claims 57-59, 61, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Thiry (*J Gen Virol* 2:143-153). The claims are drawn to (in relevant part) a method for treating eukaryotic infections caused by viruses using programmed -1 ribosomal frameshifting by exposing eukaryotic cells infected with a virus that uses -1 ribosomal frameshifting to sparsomycin.

Thiry teaches a method for treating fowl plague virus, equine encephalitis virus, Newcastle disease virus, vaccinia virus, and pseudorabies virus infections in chick embryo cells by administering sparsomycin (see particularly p. 149). Thiry teaches dosages of sparsomycin that reduced virus yield included 0.5 micrograms/mL (p. 149),



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which, using 361.44 g/mole as the molecular weight of sparsomycin, is 1.4 micromoles/L.

This anticipates claims 57-59, 61, and 63 as written.

### ***Conclusion***

**[19] Status of the claims:**

Claims 7, 35-43, 48-50, and 54-66 are pending.

Claims 7, 35-43, 48-50, and 54-56 are withdrawn from consideration.

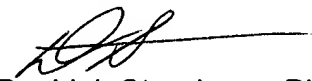
Claims 57-66 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

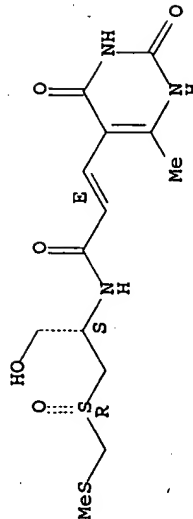
  
David J. Steadman, Ph.D.  
Primary Examiner  
Art Unit 1656

# APPENDIX A

STN Search Result

L2 ANSWER 1 OF 2 REGISTRY COPYRIGHT 2005 ACS on STN  
 RN 1404-64-4 REGISTRY  
 ED Entered STN: 16 Nov 1984  
 CN 2-Propenamide, N-[(1S)-1-(hydroxymethyl)-2-[(R)-  
 [(methylthio)methyl]sulfinylethyl]-3-(1,2,3,4-tetrahydro-6-methyl-2,4-  
 dioxo-5-pyrimidinyl)-, (2E)- (9CI) (CA INDEX NAME)  
 OTHER CA INDEX NAMES:  
 CN 2-Propenamide, N-[1-(hydroxymethyl)-2-[(methylthio)methyl]sulfinylethyl]-  
 3-(1,2,3,4-tetrahydro-6-methyl-2,4-dioxo-5-pyrimidinyl)-, [R-[R\*,S\*-(E)]]-  
 CN 5-Pyrimidineacrylamide, 1,2,3,4-tetrahydro-N-[1-(hydroxymethyl)-2-  
 [(methylthio)methyl]sulfinylethyl]-6-methyl-2,4-dioxo-, (E)-(1S)- (8CI)  
 CN Sparsomycin (7CI)  
 OTHER NAMES:  
 CN (+)-Sparsomycin  
 CN NSC 059729  
 CN NSC 59729  
 CN U 19183  
 PS STEREOSEARCH  
 DR 28277-66-9  
 MF C13 H19 N3 O5 S2  
 LC STN Files: ADISINSIGHT, AGRICOLA, ANABSTR, BEILSTEIN\*, BIOSINNESS,  
 BIOSIS, BIOTECHNO, CA, CANCERLIT, CAOLD, CAPLUS, CASREACT, CHEMCATS,  
 DDFU, DRUGU, EMBASE, MEDLINE, MRCK\*, NAPRALERT, NIOSHTIC, PHAR, PROMT,  
 PROUSDDR, RTECS\*, SYNTHLINE, TOXCENTER, USAN, USPAT2, USPATFULL  
 (\*File contains numerically searchable property data)  
 Other Sources: WHO

Absolute stereochemistry. Rotation (+).  
 Double bond geometry as shown.



\*\*PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT\*\*

218 REFERENCES IN FILE CA (1907 TO DATE)  
 23 REFERENCES TO NON-SPECIFIC DERIVATIVES IN FILE CA  
 218 REFERENCES IN FILE CAPLUS (1907 TO DATE)  
 8 REFERENCES IN FILE CAOLD (PRIOR TO 1967)

# APPENDIX B

©www.sigma-aldrich.com

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**S1667** Sparsomycin from *Streptomyces sparsogenes*

Sigma ≥98%

